

DRAFT of Minutes for January 3, 2002

Genetics Task Force Meeting

The Washington State Board of Health Genetics Task Force convened its first meeting on January 3, 2002 at the Cherberg Senate Building, Hearing Room 4 in Olympia, WA. Linda Lake, Genetics Task Force Chair, called the meeting to order at 9:10 a.m.

The Genetics Task Force members and staff introduced themselves.

The following Genetics Task Force members attended the meeting:

Linda Lake, Chair	Robert Miyamoto, Ph.D.
Philip Bereano, Ph.D.	Vicki Hohner, M.B.A.
Peter Byers, M.D.	Maxine Hayes, M.D., M.P.H.
Joe Finkbonner, RPh, MHA	Nancy Fisher, M.D., M.P.H., R.N.
Helen McGough	Howard Coleman
Suzanne Plemmons, R.N., M.N., C.S.	Robin Bennett
Ty Thorsen	Wylie Burke, M.D., Ph.D.
Brenda Suiter	C. Ronald Scott, M.D.
Julie Sanford-Hanna, Ph.D.	Amanda DuBois, J.D.
Mellani Hughes, J.D.	

The following Board of Health Genetics Task Force Staff attended the meeting;

Don Sloma, Board of Health Executive Director
Desiree Robinson, Executive Assistant to the Board
Jennifer Dodd, Assistant to the Board
Candi Wines, Genetics Task Force Coordinator
Joan Mell, JD, Genetics Task Force Legal Consultant

The following invited guests/speakers attended the meeting:

Mike Glass, Policy Liaison for WA State Newborn Screening Program
David Eaton, Ph.D., Director, University of Washington Center for Ecogenetics and Environmental Health
Debra Lochner-Doyle, C.G.C., Manager Genetic Services Section Washington State Department of Health

Linda Lake reviewed the 2001-2003 biennium budget proviso establishing the Genetics Task Force (GTF). Chair Lake reviewed the role of the Board of Health and the responsibilities of the GTF. She stated that the The GTF's work is outlined in the state biennial budget proviso, approved by the legislature. and the GTF must be a forum for discussion on topics that are represented by many viewpoints, opinions, and degrees of knowledge. The group has the opportunity to not merely have serial recitations of points of view, opinions, or staunch beliefs but put ideas in front of each other in order to have meaningful discussions and come to appropriate recommendations for the legislature.

Summary of Work Plan and Staff Announcements

Candi Wines discussed the Work Plan. She also indicated that the timeline for meetings has been revised; see the Proposed 2002 GTF Meeting Schedule. Ms. Wines issued a reminder that GTF members can recommend speakers, discussion topics or resources for future meetings by contacting her via phone or email.

Questions/Discussion

Dr. Phil Bereano suggested that the charge from the legislature is broader than issues of privacy and discrimination; stem cell research and cloning are not explicitly excluded. He suggested that the GTF members should have a discussion about the scope of work. Dr. Bereano offered materials for reference regarding legislation in other states (summary of legislation organized by state, compiled by the Council for Responsible Genetics). Chair Lake clarified that the Work Plan was developed and approved by the Board of Health, any changes made to it, must also be approved by the BOH.

Dr. Nancy Fisher indicated that while there may not be specific laws in WA State regarding genetic discrimination, some existing laws may be relevant to the issue and the GTF must be sure to consider those and not duplicate efforts.

Joan Mell, JD - Presentation on DNA Legislative History in WA State

PowerPoint presentation available on the GTF website and in hard copy in the meeting binders.

Comments from Senator Rosa Franklin and Representative Al O'Brien

Senator Rosa Franklin

Senator Franklin indicated that she became involved in writing and introducing DNA-related legislation 5-6 years ago after concluding that existing state laws did not provide adequate protection from genetic discrimination or protection of privacy. Senator Franklin speculated that while genetic testing for screening for health insurance is reported to be modest at this time, it is expected that this approach will be used more widely and may create a 'genetically uninsurable' or 'genetically unemployable' underclass. She cited a survey indicating that 1/2 to 2/3 of health insurers said they would use genetic test results if permitted to do so. Senator Franklin stressed that we must find a balance between personal rights, social benefits and health care advances – state laws and policies must make people feel safe so that they will use the technology for their benefit. She urged that the time has come for resolution and policies related to the prevention of negative effects of DNA technology.

Representative Al O'Brien

Representative Al O'Brien stated his concern is that there must be a balance between research and individual privacy. He mentioned his legislative efforts such as Bill 1902 which aimed to protect individual rights; he plans to introduce this legislation again this session. He stated that he felt there was a rush to move forward to create legislation that might limit or restrict research. He emphasized that we must consider the consequences

of legislation that aims to protect individual rights; even if the motives to protect individual rights are well meaning, there may be some unintended consequences. He discussed the economic influences acting on the issue. For example, genetic/medical research companies are moving in to Washington, providing an economic advantage for the region. He asked the GTF to consider if federal legislation takes care of the issues and reminded the members that WA law does not necessarily need to be stricter than federal law. He indicated that the legislation creating the GTF explicitly states that the GTF is to specifically address discrimination and genetic research. He emphasized that there is no money in the budget to examine more issues at this time.

Questions/Discussion

Senator Franklin agreed with Representative O'Brien's assessment of the GTF's scope of work.

Dr. Maxine Hayes reiterated the need to strike a balance between individual privacy and research/advancements; there is a need to have adequate protections to ensure the progress of the science. Senator Franklin stated that balance has been a recurring theme, but there is a point in time where a solution must be reached. She encouraged the GTF to look at how public policy can be crafted to protect the individual and bring a sense of resolution against the fear in order to stimulate participation in research. Representative O'Brien stressed that research is very important, and legislators are looking for some way to balance privacy rights with research efforts. He suggested that the GTF was created as a means to consolidate all the available information and make informed recommendations to the legislature.

Howard Coleman brought up the idea that including genetic information/DNA under protections that already exist for health/medical information seems like an obvious solution and asked Senator Franklin and Representative O'Brien to please address this. Senator Franklin indicated that this approach had been attempted, especially in context to HIPAA and anti-discrimination laws. Efforts were made to amend genetic information on to anti-discrimination laws and the legislation did not pass. Senator Franklin stated that she has no intention to introduce any other DNA/genetics related bills while the GTF continues to meet; she will wait for the GTF's report.

Dr. Bereano inquired whether the 47 other states that have legislation have an exemption for commercial or academic research and if researchers in other states have had their work impeded by the fact that there are no research exemptions in the laws? Dr. Bereano asked the staff to get more information about this.

Dr. Fisher reminded the GTF that as the members look at the effect of genetics on society, they have to look at how it affects employment and all types of insurance (health, life, disability). She indicated that there are many laws in this state that protect medical information; she suggested that some of the fears mentioned by Senator Franklin and others may be unfounded because there are some laws that do provide protection but people are not educated about them. Dr. Fisher asked if there are laws that protect the use of samples taken for one purpose but used for another? Senator Franklin stated while

WA does have some privacy laws, the privacy laws do not have the scope of protection she is looking for.

Representative O'Brien said that one focus of the GTF must be to consider educating the public and the legislature about genetic information and how it is used, what are potential future applications, how are databases constructed, etc.

Dr. Robert Miyamoto suggested that there seems to be a lack of consensus on issues of language. He inquired about whether or not this should be one of the outputs from the GTF. He asked about what the GTF is supposed to produce for the legislature. Senator Franklin commented that definitions are one thing the GTF can provide. Dr. Miyamoto expressed concern that legislation comes down to language and interpretation and even universal, widely accepted language can be interpreted differently. Senator Franklin said that in regards to terminology, it is always necessary to define what the words mean. Proper recommendations can be made by using and clearly defining the terminology.

Chair Lake asked about why something hasn't happened given all the work already done. Representative O'Brien suggested that people were rushing and their efforts were stopped to prevent the creation of laws with long term, unwanted consequences. Senator Franklin expressed her opinion that barriers have changed along the way, and that one big barrier is the "impede research" argument, but appropriate legislation will not impede research.

Dr. Peter Byers inquired about any adverse consequences of having no legislation during this time. Representative O'Brien reported that he hasn't seen anything in terms of personal privacy violations and research has continued to move forward.

Robin Bennett indicated that there is a huge fear among the public because of lack of protection and poor counseling by physicians. Ms. Bennett stated that there needs to be a big push to educate people about existing laws that protect patients or a law needs to be created to protect patients if none exist. Ms. Bennett requested to see the data shown to other committees.

Senator Franklin brought up the idea that things/events often go unnoticed until media expose them. She said that this should be prevented in WA. Dr. Bereano suggested that government is likely not to hear about privacy violations or discrimination because people don't want to make it public. He cited a study by Dr. Paul Billings and requested that this article be provided to the GTF.

Dr. Hayes requested information about what has happened regarding genetics discrimination and privacy in other states.

Dr. Dave Eaton and Dr. Wylie Burke Presentations – Introduction and Update to the Fundamentals of Genomics

PowerPoint presentations available on the GTF website and in hard copy in the meeting binder.

Lunch

Meeting reconvened at 1:17 p.m.

Debra Lochner-Doyle presentation - Newborn Screening Program in Washington State

PowerPoint presentation available on the GTF website.

Questions/Discussion

Debra Lochner Doyle stated that her office logs calls from people who feel that they have been victims of discrimination or privacy violations (names are not associated with the call records). She volunteered to provide this data. Her office has also conducted forums, surveys and focus groups of people in WA State regarding genetics issues.

Dr. Bereano requested a copy of the confidentiality agreement signed by DOH staff and contractors.

Chair Lake inquired about whether a researcher has requested access to the NBS database/information and been denied? Mike Glass reported that no requests for access have been denied, but the DSHS/DOH Human Subjects Review Board has required modifications of study proposals to help tighten security and privacy protections. He also reported that most requests are from individuals and not from researchers.

Chair Lake inquired about the general uses of the data in terms of reports generated from it. Ms. Lochner-Doyle reported that hospitals receive quarterly reports regarding quality control and compliance with data collection. Annual reports are also generated.

Dr. C. Ronald Scott mentioned two other examples of the use of the system – 1) it is a database of all children in the state and it can be used to find missing children (Mr. Glass confirmed that the information has been used via subpoena for that purpose), and 2) sometimes children die from unknown causes and tests can be done with the consent of the parents to determine the cause.

Vicki Hohner – HIPAA and Genetics Privacy

PowerPoint presentation is available on the GTF website and in hard copy in the meeting binder. HIPAA information website <https://wws2.wa.gov/dshs/maa/dshshipaa/>.

Questions/Discussion

Dr. Hayes inquired about how the WA state laws are being compared to HIPAA for compliance. Ms. Hohner stated that the only thing that is being done is comparing each provision with HIPAA.

Dr. Byers inquired about Ms. Hohner's mention of other states that have passed laws and had to repeal them; he requested more information about this. Ms. Hohner reported that some of those laws were more broad than health information (e.g. they applied to

financial information, etc) some were too restrictive and created too much of a burden so nothing could get done.

Chair Lake inquired about the enforcement of HIPAA regulations. She observed that HIPAA gives the right to bring suit for violations, but doesn't provide for inspection. Given this, she asked if compliance was 'voluntary'. Ms. Hohner reported that there is a plan to introduce legislation on enforcement. Current HIPAA law states that anyone can complain to HHS and HHS can inspect and impose penalties.

Helen McGough inquired about JCAHO (Joint Commission for the Accreditation of Healthcare Organizations), are HIPAA standards incorporated into such accreditation programs? Ms. Hohner responded that some accreditation programs are starting to incorporate HIPAA standards- e.g. JCAHO. She reported that applying the requirements to the licensing process is still in discussion.

Dr. Byers inquired as to what is the basic assumption behind the idea that something as comprehensive as HIPAA is required and what are the costs of implementing it? What are benefits of it? Ms. Hohner responded that costs are going to vary state to state because the laws vary.

Dr. C. Ronald Scott offered a case scenario of referral and consultation with other health care providers – does HIPAA affect these exchanges? Ms. Hohner reported that for the purposes of treatment there are no limitations to the exchange of information.

Howard Coleman inquired about standards for electronic medical records. Ms. Hohner responded that electronic records were part of the original law and that 11 more HIPAA regulations are expected; it is possible that some amendments to the privacy section will be made.

Dr. Byers inquired as to whether HIPAA is similar to ERISA by excluding a large portion of providers, agencies, etc? Ms. Hohner responded, no, HIPAA is much more broad reaching.

Chair Lake asked Ms. Hohner to speculate, about whether or not genetic information that could be potentially harmful is protected. Ms. Hohner responded that it is protected only within the boundaries of HIPAA, i.e. it is protected if it is in the hands of healthcare entities and their contractors. One drawback of HIPAA is that it does have boundaries. Dr. Miyamoto asked if the information is protected by another regulation. Is there something else that guards that information outside of the health system? Ms. Hohner responded, no, not at the national level. Dr. Miyamoto asked if there are cases where genetic information is not protected. Ms. Hohner responded that any health information is limited by the boundaries of HIPAA, including genetic information.

Dr. Wylie Burke asked whether or not genetic information obtained within a health care setting for the purpose of health care is protected by HIPAA from being released outside of the health care system? Ms. Hohner – No. The information can leave the health care

system by other means (e.g. subpoena or other requests allowable by law). HIPAA protections are limited to the health care industry and the information is not protected outside of the healthcare system. Dr. Burke indicated that she was specifically concerned with whether or not insurers can get access to information obtained in a health care setting. Ms. Hohner responded that this is not directly addressed in HIPAA, but insurers are subject to the same requirements. Dr. Burke stated that an important distinction is that the privacy protections put in place by HIPAA do not limit the type of information an insurer can ask for directly from an individual. What laws are necessary to provide this type of restriction? Dr. Bereano added that this is the same issue for employment and what employers can ask for.

Joan Mell Presentation - Health Care Information Act

PowerPoint presentation available on the GTF website and in hard copy in the meeting binder.

Joan Mell began her presentation with a clarification of a question in the previous discussion regarding whether HIPAA protects against use of genetic information in insurance – she stated that there is a piece in the statute itself that precludes the use of genetic information for insurance purposes.

Dr. Bereano replied that this only applies to not denying someone insurance, it does not put limits on rate setting; he emphasized that this is an area where a law regarding discrimination will be useful.

Joan Mell Presentation - Case law

PowerPoint presentation available on the GTF website and in hard copy in the meeting binder.

Questions/Discussion

Dr. Bereano suggested that the Norman-Bloodsaw v. Lawrence Berkeley Laboratories case may also be a relevant case for the GTF to review.

Helen McGough presentation - IRB guidelines

PowerPoint presentation available on the GTF website and in hard copy in the meeting binder.

Questions/Discussion

Dr. Bereano asked if HIPAA covers individual insurance. Ms. Hohner replied by saying that this is part of the larger portability piece and it is not in the privacy rule; she will go back and look at it.

Dr. Byers asked if there is a statement by the colleges regarding research use of genetic information? Ms. McGough replied that there are a couple of letters to HHS Secretary Tommy Thompson and she will provide them to the GTF.

Vicki Hohner asked if federal level efforts to tighten IRB requirements address these issues? Ms. McGough responded no.

Dr. Fisher asked if there is any internal quality assurance? Ms. McGough replied that at the University of Washington there are several levels of review within the office. A regular audit process is conducted by the FDA once every 3-years at minimum, and IRBs can be spot audited by Office of Human Research Protections. The University of Washington Human Subjects Division has not been audited on a for-cause basis but they have requested an audit for educational purposes.

Ms. Hohner noted that most of the breaches in privacy and confidentiality do not occur in government or research, most are in the private sector.

Dr. Byers suggested that it is very important to define what/who it is we are trying to protect, how we want to protect them and what information we want to use.

Chair Lake closed the meeting with an overview and a look ahead to the next meeting, which will be on evidence of genetic discrimination and privacy violations and policies in other states. She asked GTF members to please make information and resources available to staff for the next meeting or future meetings. She also requested that they bring forth information on any topics discussed today.

Open Discussion

Dr. Nancy Fisher offered to give a presentation on eugenics and an overview of the historical perspective of genetic discrimination. Julie Sanford-Hannah requested more information about the role of insurance. Robin Bennett requested information about insurance databases. Dr. Wylie Burke requested a review of how state law limits use of pre-existing conditions for insurance coverage. Dr. Phil Bereano recognized that no one from an employee's union perspective is on the GTF and requested that the staff try to get people to represent these perspectives. Mellani Hughes requested information on how WA State law addresses discrimination in employment.

Chair Lake adjourned the meeting at 4:00 p.m. The next GTF meeting is scheduled for February 25, 2002